The role of simulation tools to innovate the prosthesis socket design process

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Abstract

The products having a tight interaction with the human body require an high level of customization in order to fulfill comfort, usability and wearibility requirements. The prosthesis socket for lower amputees is an example of this kind of products. At present, the manufacture of a socket is almost an hand made activity performed by skilled orthopaedic technicians. With the aim to speed-up the design process and obtain more comfortable products, a computer design methodology to assist the design of such a kind of custom-fit goods is under investigation within the framework of an Italian Research Project called DESPRO. In the paper the role of the simulation tools within the methodology under development is presented according to the design tasks. The application of the FEM and explicit solution strategies to simulate the biomechanical interaction between the socket and the stump of the patient is described. The use of shape optimization tools to speed-up the socket design process, is also, investigated and discussed. Some preliminary results of the suggested approach are introduced.

Keywords: Prosthesis socket, Finite Element Analysis, Custom-fit product design, stump-socket interaction

1. Introduction

The products having a tight interaction with the human body require an high level of customization in order to fulfill comfort, usability and wearibility requirements. Due to the strong dependence on the human shape, the design and manufacturing of such a kind of products cannot be addressed using tools and methods employed in the industrial field but they require the definition of "ad hoc" methodologies.

The prosthesis socket for lower amputees is an example of this kind of product. The socket is the counterpart of the prosthesis having the function to support the residual limb of the patient during the stance phase and the gait cycle. The design and manufacturing of high-quality sockets must fulfill the following principles: perfect close-fitting of the prosthesis to the stump in order to avoid the relative motion that may cause pain and discomfort, good response to forces and mechanical stress, safety and stability, tight connection to the stump anatomy without affecting blood circulation.

At present, the manufacture of a socket is almost an hand made activity performed by skilled orthopaedic technicians, and CAD/CAM tools for this kind of products are not able to manage all the product development stages, from design to manufacture. The hand-made production process consists of the following main phases:

- manual measurement of the stump from under patella to fibula apex for transtibial and from greater trocanther to femoral apex for transfemoral;
- realization of the negative plaster-cast directly on the patient's stump using chalk and bandages exerting pressures to ensure the correct load points of the stump in the socket;
- production of positive plaster model;
- comparison of the positive cast measurements (acquired as done for the patient's stump) with those taken on the patient in order to verify the cast model accuracy and if necessary manual adjustment of the plaster model;
- thermoforming of the styrene or polyurethane liner on the plaster model to manufacture the inner shape of the socket;
- resin lamination with a carbon fibre leaf for the socket embodiment.

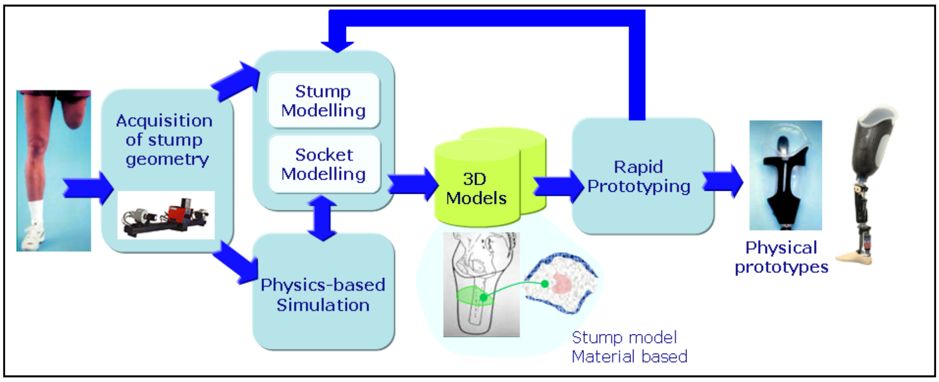

Fig. 1. The new prosthesis socket design process.

Since this process is carried out by hands, it is very time consuming and requires not negligible efforts to optimize the comfort of the prosthesis according to the anatomy of the patient. With the aim to overcome these limits, a computer design methodology to assist the design of such a kind of custom-fit products is under investigation within the framework of an Italian PRIN Project (Research Project of National Interest) called DESPRO (Integration of Innovative Methodologies to DESign and Develop Custom-fit Products: Application and validation for a Socket of a Lower Limb PROsthesis) funded by Italian Research Ministry. The consortium consists of four universities, University of Bergamo, Florence, Udine, and Polytechnic of Milan with the collaboration of an Italian prosthesis manufacturer named Centro Protesi INAIL, Budrio (BO). The approach under development in this project [1] is based on the integration of different kinds of computer aided tools, and it has been designed with the aim to implement best practices used by orthopaedic technicians in order to ensure high-level products independently of the competencies of the domain expert that produces the socket. According to Fig. 1, it consists of the following steps and techniques:

- reverse engineering tools for the acquisition of patient's morphology and bony-muscular structure (in this case the residual limb) both under static and dynamic conditions.
- a physics-based modeller allowing the designer to represent a product as composed by different materials (inner parts modelling);
- an environment for physics-based simulation to reproduce the real behaviour of socket-stump system with the aim to support the optimization of the socket shape;
- Rapid prototyping tools for the realization of the physical prototypes of the socket.

In the outlined road-map, the physics-based modelling and simulation of the interaction socket-stump during the socket design process play a fundamental role.

The aim of this paper is to describe the simulation strategy under investigation and to discuss main problems and open issues regarding its integration in the road-map. In Section 2 the simulation tasks will be described according to the purpose of the project and a review of tools and methods developed to address such a kind of problems is summarized. Section 3 describes the simulation and optimization approach under investigation in the project and the preliminary results of its application to a trans-tibial prosthesis socket. Eventually, in Section 4, discussions on the proposed approach are performed and further developments are briefly summarized.

2. Simulation of the socket – stump interaction: tasks and state of the art.

As stated in [2], soft tissues of the residual limb within a prosthetic socket are subjected to a critical environment. Due to the loads experienced during the gait cycle, pressures and shear forces are applied by the socket on the limb, although the limb tissues are not able to support such loads. Moreover if excessive slip exists between the skin of the residual limb and the socket, tissue abrasion can occur causing physiological damage of the biological tissue. In order to make the prosthesis comfortable, the socket shape should fit in a tightness way the residual limb of the patient without generate concentrated loads during the gait. Besides the shape of the socket should allow an easy wearibility by minimizing the skin and tissue distortion during the donning phase. According to this statement, the objectives of the simulation phase are to obtain the load distribution in term of pressure and shear stress at the stump-socket interface during the gait cycle and to evaluate the wearibility of the socket by verifying the presence of dangerous undercuts that may cause large tissue deformation during the donning phase. These results will guide the optimization of the socket shape.

The modelling and simulation of the socket-stump biomechanical interaction is a very hard task to accomplish since there are many critical factors to be considered, such as: the strong nonlinear mechanical behaviour of the biological tissue that exhibits large deformations and the hard contact conditions due to the irregular geometry of the stump surface. In the last years many researches have been carried out to obtain models able to simulate the interaction between soft tissues and hard materials. Two main approaches have been adopted: the Particle-based modelling and Finite Element Method.

In [3] the authors present a method able to simulate the muscle deformations in real-time using a linear mass-spring system. In [4] a soft tissue simulator for aesthetic surgical operations is presented. This system uses a fast tetrahedral mass-spring model to calculate soft tissue deformation due to the interaction with the bones in a short time interval. In [5] a linear mass-spring model has been described to simulate the interaction between the surgical tools and the human soft tissue during suturing operations. As stated, all these kinds of models have been largely adopted only for real-time simulation and visualization purposes. Even if this technique is computationally cheaper, it requires a discretization of the continuum in terms of mass and spring elements: these parameters are very difficult to be tuned according to the mechanical behaviour of the soft tissue.

Finite Element Method (FEM) has been largely adopted to simulate the prosthetic socket – residual limb interaction as reviewed in [6, 7]. More recently the effects of the inertial loads and contact conditions on the interface between prosthetic socket and residual limb of an amputee during the gait, have been studied in [8, 9]. The pressure distribution at the socket-limb interface has been determined by means of a 3D finite element model based on the geometry of the residual limb, the internal bones and the liner; the soft tissues have been modelled as linear elastic. In [10] the authors have developed a FE model composed of a socket, liner and residual limb by which to simulate the socket interface behaviour under quasi-static loading conditions. The load boundary conditions have been derived by measuring the ground reaction forces during the gait. All the soft tissues have been modelled as linear elastic. A finite element model to predict the pressure at the stump-socket interface is presented in [11]. Here an integration of the CAD-FEA tools for socket design purpose is, also, presented and the soft tissue are modelled as linear elastic.

In reviewing the afore-mentioned researches two main issue are still open: the material model adopted for the soft tissue and the simulation of the donning phase under friction hypothesis between the socket and the stump. The use of the FEM as socket design tools, is still limited by the linear elastic approximation of the soft tissue behaviour, more accurate results in terms of pressure distribution may be obtained using non linear material models as shown in [12, 13]. Here the authors have developed a non linear viscoelastic material model of the soft tissue by performing "in-vivo" indentation tests of the residual limb of the patient. The slippage and friction conditions between the socket and the stump and the large deformations that the surface of the stump experiences, make very difficult to simulate the donning using FEM. In the related works such a kind of task has been addressed by prescribing displacement boundary conditions on the surface of the stump corresponding to a given socket shape. This approach produce not negligible errors between the simulated donning and the real donning of the socket since the stretching and distortion of the soft tissue, due to the sliding of the stump into the socket, are not taken into account and the presence of undercuts cannot be identified.

Since one important objective of this work is to perform an accurate simulation of the socket-stump interface, the afore-mentioned researches suggest that the FEM supplies better qualitative and quantitative results with respect to the particle-based modelling approach, even if this one requires less computational efforts. However in order to use the FEM for socket design and optimization purpose, more accurate materials model should be used to represent the behaviour of the soft tissue and more suitable solution strategies are required to deal with the strong non linearity of the problem.

3. Simulation tools to support the socket design in the DESPRO project

The approach under investigation in the DESPRO project to support the design of the prosthesis socket is based on FE analysis. By means of FEA tools the biomechanical behaviour of the socket is simulated, then the results obtained are used as responses to perform the modification of the socket shape.

The simulation is divided in two steps: first the virtual donning of the socket on the stump is performed and after the gait cycle is applied. By the donning simulation the designer can verify if the shape of the socket allows the wearibility by the user. In this way the shear stress on the stump-socket interface can be evaluated so that the stretching of the soft tissue due to the contact friction may be taken into account. The gait simulation allows the characterisation of the biomechanical behaviour of the socket-limb interface during the walking of the patient. The time-dependent loads acting during the gait are applied to the physics-based models of the socket and the stump. Such a kind of data may be obtained by experimental tests or, at least, via literature. The criteria guiding the optimization of the socket shape are:

- to avoid pressure peaks on the stump (pressure peaks should be less than the pain threshold tolerance of the patient);
- to avoid undercuts of the socket shape along the donning direction;
- to minimize the weight of the socket.

The stress in the socket is also evaluated in order to verify the compliance with the structural specifications.

3.1. FEA tools and FE modelling

To carry out the previously described simulations, the FE explicit code LS-DYNA rev. 9.70 has been adopted. The use of the explicit solution strategy allows managing simulation problems that are characterized by large deformations and hard contact conditions in a suitable way. The explicit solver allows to use contact models that do not require to define the contact surfaces; indeed this solution strategy is able to deal with problems where the contact surfaces are a priori unknown such as in the case of the donning simulation phase where, due to the large deformations of the soft tissue and the irregular geometry of the stump, the contact surface changes a lot during the simulation. Moreover, in terms of computational efforts, the explicit code is more efficient and faster than the implicit one for such a kind of problems.

The FE models of the stump is built starting from the 3D CAD model obtained by Reverse Engineering of the residual limb of the patient. Its geometry is reconstructed by using two different technologies: the 3D laser scanner, and the Magnetic Resonance Imaging technique. For the external part of the residual limb the 3D scanner was used while to reconstruct the solid geometry of the internal bone, MRI is employed [14]. This allows building an FE model of the stump that takes into account both the soft tissue (such as skin and muscles) and the bones according to the anatomy of the limb. All these parts are meshed using 3D explicit tetrahedral solid elements.

The first socket model is simply made by modifying the offset surface of the limb skin, so the internal shape has the same external shape of the stump. This surface is meshed using 3D explicit shell elements with constant thickness. In fig. 2 the stump-socket FE assembly of a trans-tibial amputee, ready to perform the simulations is shown.

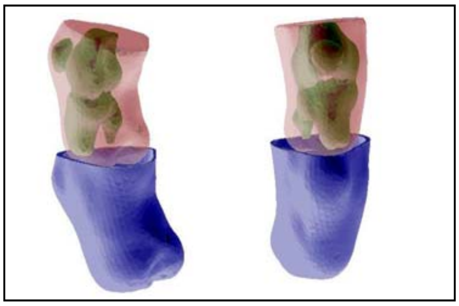

Fig. 2. The FE model of the socket-stump assembly: the stump model is constituted by a two layered assembly that takes into account the skin, the muscles and the bones.

The automatic bucket sort contact algorithm is used to search the contact during the simulation. Such a kind of model does not require to define the counterparts that may undergo in contact but just the contact parameters such as the friction coefficient.

3.2. Material models

In this preliminary phase of the project in order to test the feasibility of the simulation approach only linear models have been used; for the bones, one with Young's modulus equal to 10 GPa, for the socket, a second linear elastic material with Young's modulus equal to 1.5 GPa, and, for the soft tissues, a third linear model with Young's modulus equal to 0.2 GPa according to the literature. However, as stated in the previous section the material model plays a fundamental role in order to obtain accurate results. Since the material behaviour depends strongly on the limb anatomy, it should be determined every times for each patient. With the aim to address this task, an hybrid method based on in-vivo indentation test and FEA simulations is under development, in order to evaluate more proper non linear bulk models of

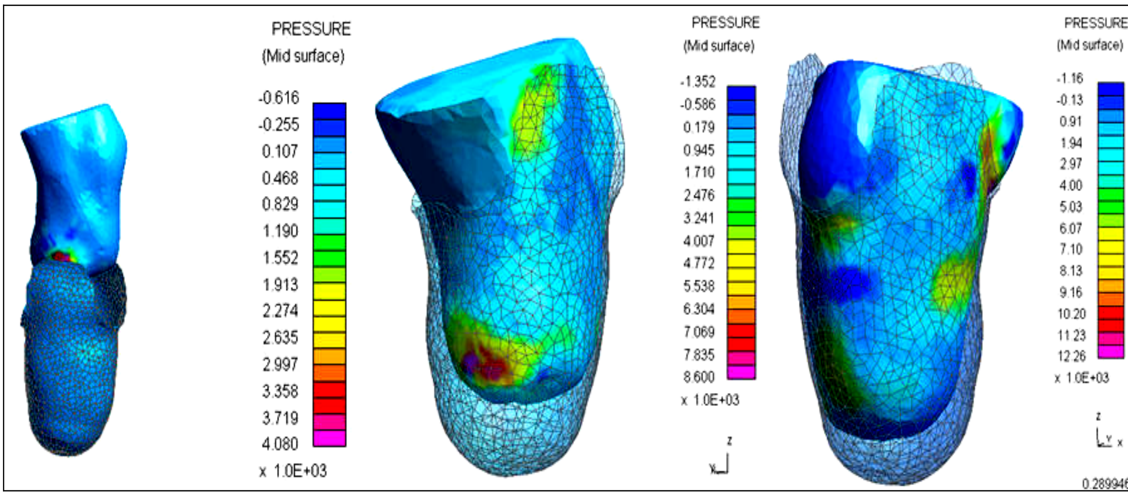

Fig. 3. Preliminary results of the suggested simulation strategy. The map of colours refers to the pressure distribution on the stump surface (Pa).

materials for highly deformable tissue (such as hyperelastic or viscoelastic models). This kind of approach allows to characterize the mechanical properties of the soft tissue in different locations of the residual limb. In this way a local material model, one for each location, can be defined according to the real stiffness distribution of the soft tissue around the bones of the limb. More in particular, the approach consists in to perform the indentation on the surface of the residual limb and measure, as a response, the load reaction at the tip of the indenter. The load – displacement curve is recorded and used to set up the unknown parameters that define the material model. This task is accomplished by an optimization problem performed via FEA where the coefficients that define a general anisotropy material model are set as design variables for the stump model. By simulating the indentation test in the same location of the virtual stump in which the experimental one is carried out, the numerical load – displacement response at the tip of the virtual indenter is obtained. The optimization algorithm iterates the simulations by changing the material coefficients until the numerical response obtained at the tip of the virtual indenter meets the experimental one. By repeating this procedure for each location where the indentation test has been performed, the material model is tuned over the entire FE model of the stump.

3.3. Simulation and optimization strategy

The donning simulation is performed by applying a load equal to half the weight of the patient, to the stump. This load is maintained until the complete donning of the socket is reached. In this way, the pre-stressed conditions on the stump due to the tissue deformations during the donning phase of the socket are obtained. This stress takes into account the shear due to the friction between the stump and the socket surface so that the real stretching of the soft tissue can be simulated. When the donning of the socket is completed, the gait load cycle is simulated. The load that the stump experiences during the gait are applied in term of time-dependent components reduced to the prosthesis socket. At the beginning of this simulation the stump preserves the pre-stressed condition history experienced during the donning phase so that the real pressure distribution can be obtained. In the figures 3 the preliminary results of the feasibility of such a kind of approach are shown. Here the donning simulation and the pressure distribution reached on the stump surface of the patient are presented. Once such a kind of simulations have been performed, the model of the socket is modified by the technicians according to the criteria above described. By iterating the modification-simulation cycle the optimal shape of the socket will be reached.

In order to speed-up the optimization phase, the integration of Shape Optimization tools is, also, under investigation. The main issue to address is the setting up of the optimization problem according to the comfort specifications to be fulfilled. As stated in the literature, the pain pressure threshold is the upper limit of the contact pressure that a patient can tolerate without perception of discomfort. A criterion to define the optimization task may be to find the shape of the socket that maximize the difference among the pain pressure and the real pressure over the entire stump surface. The problem is represented by the fact that the pain threshold is strongly dependent on the patient perception, the limb anatomy and the material of the socket (some areas of the limb can tolerate more or less pressure than others, as described in [15], the average value of the pain pressure threshold ranges from 0.5 to 0.8 MPa). This requires to measure the pain pressure tolerance by performing in vivo indentation test on the patient and to define different design domains on the mesh of the socket according to the pain pressure distribution. Another important issue is how to take into account the wearibility requirements in the optimization process. In order to avoid undercuts on the socket shape, the design must be drawn along a preferred direction that considers the stump donning trajectory. In general terms, this kind of problem is the same that must be addressed when a part is manufactured by casting process, where the shape should be designed taking into account the sliding direction from the die. In the Shape Optimization tools a set of manufacturability constraints to perform this task is available so their application to the socket shape design may be a possible way to take into account the wearibility requirements in the socket optimization process.

4. Conclusion

In this paper the role of the simulation tools to innovate the design of a custom product such as the socket prosthesis has been introduced.

The objectives of the simulation phase have been described according to the task of the DESPRO project. The simulation approach under investigation to support the design of products characterized to have a tight interaction with the human body has been, also, summarized. Further improvements of such a kind of approach have been briefly introduced and discussed. These developments go towards the implementation of an hybrid method based on the integration of indentation tests and FE analysis in order to define more accurate material models able to represent the mechanical behaviour of the soft tissue. Moreover a possible way to integrate Shape Optimization tools in the simulation phase as a means to speed-up the socket design process, has been identified and discussed.

Eventually, experimental tests in order to measure the pressure distribution at the socket – stump interface have been planned with the aim to check the validity of the proposed simulation approach.

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